

15

3. The vaginal suppository of claim 1, wherein the estradiol is micronized.

4. The vaginal suppository of claim 1, wherein the estradiol is hydrated.

5. The vaginal suppository of claim 1, wherein the suppository comprises from about 1 microgram to about 10 micrograms of estradiol.

6. The vaginal suppository of claim 1, wherein the suppository comprises about 10 micrograms of estradiol.

7. The vaginal suppository of claim 1, wherein the suppository comprises about 5 micrograms of estradiol.

8. The vaginal suppository of claim 1, wherein the suppository comprises about 2.5 micrograms of estradiol.

9. The vaginal suppository of claim 1, wherein the suppository further comprises a capsule.

10. The vaginal suppository of claim 9, wherein the capsule is a soft gelatin capsule.

11. The vaginal suppository of claim 1, wherein the solubilizing agent comprises at least one of an ester of caproic fatty acid, an ester of caprylic fatty acid, an ester of capric fatty acid, and combinations thereof.

12. The vaginal suppository of claim 1, wherein the solubilizing agent comprises a monoglyceride, diglyceride, or triglyceride ester of the at least one C6-C12 fatty acid.

13. The vaginal suppository of claim 12, wherein the solubilizing agent comprises a caprylic/capric triglyceride.

14. A vaginal suppository comprising:

- (a) a pharmaceutical composition comprising:
 - a therapeutically effective amount of estradiol;
 - a caprylic/capric triglyceride;
 - a non-ionic surfactant comprising PEG-6 palmitostearate and ethylene glycol palmitostearate; and

16

(b) a soft gelatin capsule,

wherein the pharmaceutical composition comprises from about 1 microgram to about 25 micrograms of estradiol; wherein estradiol is the only active hormone in the pharmaceutical composition; and

wherein the pharmaceutical composition does not include a hydrophilic gel-forming bioadhesive agent.

15. A method of treating an estrogen-deficient state, the method comprising administering to a female in need thereof, a vaginal suppository comprising:

a) a therapeutically effective amount of solubilized estradiol; and

b) a solubilizing agent, wherein the solubilizing agent comprises at least one C6-C12 fatty acid or a glycol, monoglyceride, diglyceride, or triglyceride ester thereof;

wherein the vaginal suppository comprises from about 1 microgram to about 25 micrograms of estradiol;

wherein estradiol is the only active hormone in the vaginal suppository; and

wherein the vaginal suppository does not include a hydrophilic gel-forming bioadhesive agent in the solubilizing agent.

16. The method of claim 15, wherein the estrogen-deficient state is vulvovaginal atrophy.

17. The method of claim 15, wherein the estrogen-deficient state is an estrogen-deficient urinary state.

18. The method of claim 15, wherein the estrogen-deficient state is selected from the group consisting of: vulvovaginal atrophy, dysuria, dyspareunia, estrogen-deficient urinary states, and vaginal bleeding associated with sexual activity.

* * * * *